

RISK FACTORS

You should carefully consider all of the information in this document and, in particular, the risks and uncertainties described below, before making an [REDACTED] in our H Shares. We are affected materially by requirements and restrictions that arise under laws, regulations, judicial interpretations and government policies in nearly all aspects of our businesses in the jurisdictions where we operate.

The risks described below are not the only risks that may affect us or our [REDACTED]. Additional risks and uncertainties of which we are not aware or that we currently believe are immaterial may also adversely affect our business, financial condition, results of operations and prospects. If any of the possible events described below occurs, our business, results of operations, financial condition and growth prospects could be materially and adversely affected. The [REDACTED] of our H Shares could decline owing to any of these risks, and you may lose all or part of your [REDACTED].

RISKS RELATED TO OUR BUSINESS AND INDUSTRY

Our business and prospects depend substantially on the success of our products and product candidates. If the development or commercialization processes are unsuccessful or prolonged, our profitability and business prospects could be adversely affected.

Our long-term competitiveness depends on the development and commercialization of products and product candidates in our focused therapeutic areas. To this end, we have invested, and expect to continue to invest, significant resources in advancing our technologies, building a strong pipeline of product candidates, and expanding the indications of existing products.

While we aim to develop product candidates that are novel, highly differentiated, preferably with first-in-class or best-in-class potential, we cannot guarantee that we are able to achieve this goal. The product development process, especially the development of innovative drug candidates, is time-consuming and costly. Prior to obtaining the required regulatory approval, our product candidates must undergo preclinical studies and extensive clinical trials to demonstrate their safety and efficacy in humans. Clinical trials, in particular, are difficult to design and implement, and can take many years to complete.

The outcomes of our product development process are inherently uncertain. The outcomes of preclinical studies and early-stage clinical trials may not be predictive of success in later phases, and interim results do not necessarily predict final results. In addition, preclinical and clinical data are often susceptible to varying interpretations and analyses, and even product candidates that perform satisfactorily in clinical trials may nonetheless fail to obtain regulatory approval. There can be no assurance that our studies, trials and procedures will result in a commercially viable product or expanded indication. Failure can occur at any time during the development process, including after significant resources have been invested, due to the following factors:

- regulators, institutional review boards (“IRBs”), or ethics committees may not authorize us or our investigators to commence or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or may fail to reach, agreement on acceptable terms with prospective trial sites, contract research organizations (“CROs”), principal investigators (“PIs”) or hospitals who conduct clinical trials on our behalf, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs, trial sites, PIs and hospitals;

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- the patient enrollment may be insufficient or slower than we anticipate or patients may drop out or fail to return for post-treatment follow-up at a higher rate than anticipated;
- clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon certain product development programs;
- we may elect to, or regulators, IRBs or ethics committees may require that we or our investigators, suspend or terminate clinical research for various reasons, including non-compliance with regulatory requirements, undesirable side effects, or a finding that participants are being exposed to unacceptable health risks;
- third-party contractors, if any, used in our clinical trials may fail to comply with regulatory requirements or meet their contractual obligations in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the clinical trial, which may require that we add new clinical trial sites or investigators;
- we may fail to conduct a companion diagnostic test to identify patients who are likely to benefit from our product candidates;
- the costs of clinical trials for our product candidates may be greater than we anticipate, or changes in the applicable regulatory framework may make our R&D process more time-consuming and costly;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials may be insufficient or inadequate; and
- our product candidates may fail to demonstrate satisfactory efficacy or safety profiles, particularly in comparison with competing products.

The regulatory approval process of the NMPA, the U.S. FDA and other comparable regulatory authorities for our product candidates is lengthy and the result is unpredictable. Any failure to timely obtain these regulatory approvals could adversely affect our business prospects.

Significant time, efforts and expenses are required to bring our product candidates to market in compliance with the regulatory process, and we cannot assure you that any of our product candidates will be approved for sale. The time required to obtain approvals from the NMPA, the U.S. FDA and other comparable regulatory authorities is often unpredictable. Our product candidates could fail to receive regulatory approval in a timely manner for many reasons, including: (i) disagreement with regulatory authorities regarding the design or implementation of our clinical trials; (ii) inability to commence or complete clinical trials due to regulatory holds or safety concerns; (iii) failure to demonstrate to the satisfaction of regulatory authorities that a product candidate is safe and effective for its proposed indication; (iv) insufficient or suboptimal data collected from the clinical trials, or the failure of our clinical trial results to meet the requisite level of statistical and clinical significance; (v) failure of our clinical trials to pass the Good Clinical Practice (“GCP”) inspections; (vi) unexpected changes in regulations, testing requirements, or approval policies that render our preclinical and clinical data insufficient to support approvals; (vii) failure to pass Good Manufacturing Practice (“GMP”) inspections during the regulatory review process or in connection with our manufacturing activities; (viii) failure of our clinical sites to pass audits conducted by the NMPA or other comparable regulatory authorities, which may result in the rejection or invalidation of our clinical data; and (ix) deviations from trial protocols by clinical sites, investigators or other participants to conduct the trial in accordance with regulatory requirements.

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In addition, the NMPA, the U.S. FDA or a comparable regulatory authority may require more information, including additional analyses, reports, data, non-clinical studies and clinical trials, or questions regarding interpretations of data and results, to support approval, which may prolong, delay or prevent approval and our commercialization plans, or we may decide to abandon the development programs. Changes in regulatory requirements and guidance may also occur, and we may need to amend clinical trial protocols submitted to competent regulatory authorities to reflect these changes. Resubmission may impact the costs, timing or successful completion of a clinical trial. The policies of the NMPA, the U.S. FDA and other comparable regulatory authorities may also change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may not obtain the regulatory approvals or may lose the approvals that we may have obtained.

Furthermore, clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. Regulatory approval in one jurisdiction does not guarantee that regulatory approval will be obtained in any other jurisdiction. Approval procedures can vary among jurisdictions and may involve additional product testing, validation and administrative review. We cannot assure you that we will be able to meet the regulatory requirements of different jurisdictions. Even after obtaining regulatory approval, additional time, efforts and expenses may be required to bring our product candidates to international markets in compliance with different regulatory processes.

Failure to obtain regulatory approvals in a timely manner, or at all, or the failure to obtain regulatory approvals with the intended scope of indications, would have a negative impact on the commercial prospects of our product candidates, and may cause reputational damage to us. Consequently, we may be unable to generate revenue from such product candidates despite the significant amount of resources invested in their development, and we may be required to incur additional expenses and recognize impairment losses on our intangible assets, which could materially and adversely affect our business, financial condition, and results of operations.

Decreases in the sales volume and price levels of our pharmaceutical products may adversely affect our revenue and profitability.

Our revenue and profitability depend largely on our products' commercial success, and we may be particularly susceptible to factors adversely affecting the sales volume, price levels or profitability of these products, including: (i) the availability of substitute products and the perceived advantages of competing products; (ii) exclusion from, delayed inclusion in, or reduced coverage under, government-sponsored medical insurance programs; (iii) the impact of government pricing regulations; (iv) failure to win the bids in centralized procurement processes necessary for sales to public hospitals and other relevant medical institutions; (v) interruptions in the supply of raw materials; (vi) increases in the cost of raw materials; (vii) issues with product quality or side effects or any negative publicity on our products; (viii) intellectual property infringements; (ix) adverse changes in sales network; (x) any failure to respond to changes in needs and preferences of healthcare practitioners and patients; and (xi) unfavorable policy, regulatory or enforcement changes. Many of these factors are outside of our control, and any factor adversely affecting the sales volumes, pricing levels and profit margins of our products could adversely affect our operations, revenue and profitability.

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We operate in a highly competitive environment, and we may not be able to compete effectively against current and future competitors, which could adversely affect our revenue and profitability.

The development and commercialization of new drugs and medical devices in China are highly competitive. Our products may also face increased competition from substitute products manufactured by overseas pharmaceutical companies that are seeking to access or further penetrate the PRC market. We face competition from large domestic and multinational pharmaceutical and biotechnology companies focused on innovative therapeutics. There are a number of large pharmaceutical companies that currently market and sell products or are pursuing the development of products for the treatment of the same indications for which our product portfolio targets. In particular, we face intense competition in the development of CKM-focused innovative drugs. Some of these competitors have better resources and expertise than us. As a result, our competitors may be able to respond more quickly to changes in market demand or industry standards, or devote greater resources to the development and commercialization of their products.

The competitive landscape of our target market is constantly evolving with the introduction of next-generation treatments and advanced technologies. We cannot assure you that we will be able to respond to emerging or evolving trends by upgrading our technology platforms, enhancing our R&D capabilities, or optimizing our product portfolio in a timely manner, or at all. Our commercial opportunity could be significantly reduced or even eliminated if our competitors develop and commercialize products that are safer, more effective, more convenient, or less expensive than the products we may develop or commercialize. Our competitors also may obtain approval from the NMPA, the U.S. FDA, or other comparable regulatory authorities for their product candidates more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. They may render our product candidates obsolete or non-competitive before we can recover expenses of developing and commercializing any of our product candidates. If we are unable to increase or maintain the effectiveness and efficiency of our sales and marketing activities to remain competitive, our sales volume and business prospects could be adversely affected.

In addition, mergers and acquisitions in the pharmaceutical and medical device industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative or licensing arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. If we fail to effectively compete with our competitors or adjust to structural changes in the industries, our revenue and profitability may be materially and adversely affected.

Failure to achieve or maintain market acceptance for our products could have an adverse impact on our profitability and business prospects.

The commercial success of our existing and future products depends on the degree of market acceptance they achieve among the medical community, particularly physicians and other healthcare professionals, medical institutions and third-party payers. The acceptance of our products will depend upon various factors, including: (i) the demonstrated safety and efficacy of our products, and the prevalence and severity of any adverse events or side effects; (ii) the pricing and cost-effectiveness of our products relative to alternative therapies or competing products; (iii) the perceived advantages and disadvantages of our products, including the prevalence and severity of side effects, compared to competing products or treatments; (iv) the effectiveness of our sales and marketing strategies; (v) publicity and public perception concerning our products or competing

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products, or the relevant therapeutic areas; (vi) our ability to anticipate and respond to changes in needs and preferences of healthcare practitioners and patients; and (vii) the availability and extent of reimbursement coverage for our products in key government medical insurance schemes.

If our products fail to achieve or maintain broad market acceptance, or if new products or treatments introduced by our competitors are perceived more favorably by healthcare practitioners and patients, our products may be rendered obsolete or less competitive, and the demand for our products may decline. As a result, our profitability and business prospects may be materially and adversely affected.

In addition, the actual market size for our product candidates may differ from our estimates due to various factors such as lower-than-expected market acceptance, pricing pressures, and patient availability. The number of patients in our addressable markets may prove smaller than we expect, or we may face challenges in identifying or accessing new patients. Any of the above unfavorable developments could adversely impact our business, financial condition and results of operations.

Our sales may be affected by the level of medical insurance reimbursement patients receive for using our products.

The commercial success of our products is related to the availability and extent of reimbursement coverage under government-sponsored and private health insurance programs for treatments using our products. In China, patients are typically reimbursed for products listed in the National Reimbursement Drug List (“NRDL”) and, where applicable, relevant provincial medical insurance catalogs or supplemental provincial insurance schemes (such as special medications programs for major diseases). As of the Latest Practicable Date, 32 out of our 44 marketed drugs have been included in the NRDL. The determination to include a pharmaceutical product in government-sponsored insurance coverage depends on various factors, including the product’s efficacy, safety profile and cost-effectiveness, many of which are beyond our control. Furthermore, government authorities may, from time to time, review and adjust the scope of reimbursement for products that are listed in any medical insurance catalog. We cannot assure you that our products and product candidates, if approved for commercial sale, will be included in the medical insurance reimbursement list at all times, or at all.

In addition, the governmental insurance coverage or reimbursement level in China for medical devices varies from region to region, as local government approvals for such coverage must be obtained in each geographic region in China. We cannot be certain that the government policies for medical device reimbursement will be favorable to us in the future.

In the absence of medical insurance coverage for the use of our products, patients may choose alternative treatment methods, and hospitals may recommend alternative treatments, which would reduce demand for our products and our sales. Moreover, we may need to lower the prices of our products in order to have them included in the medical insurance reimbursement list, and such price cut and reimbursement may not necessarily lead to increase in our sales and our results of operations may be adversely affected.

If we are unable to succeed in tender processes to sell our products to PRC public hospitals and other medical institutions, we may lose market share and our revenue and profitability could be adversely affected.

During the Track Record Period, we primarily sold our pharmaceutical products to distributors who then sold to end-customers which include public hospitals and other medical institutions owned or controlled by government authorities in China. Each of these institutions must generally procure

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pharmaceuticals through a centralized pharmaceutical procurement platform organized by local government authorities, and source substantially all of their pharmaceuticals through a centralized tender process. We and our competitors submit bids in such tender process to supply pharmaceutical products to these institutions at specified prices. The relevant government authorities evaluate these bids based on a number of criteria, such as bidding price, product quality, clinical effectiveness and reputation and after-sales service of the manufacturers. If we succeed in the tender process, the relevant products will be sold to the public hospitals and other medical institutions at the bid prices through our distributors, which is the primary determinant of the prices at which we sell these products to our distributors.

We may fail to win bids in a tender process due to various factors, including reduced demand for the relevant product, uncompetitive bidding price, failure to meet certain quality requirements, insufficient service quality to meet tender requirements, perception that our product is less clinically effective than competing products or our service or other aspects of our operations are less competitive. If our products are not selected in the tender processes in one or more regions, we will be unable to sell these products to the public hospitals and other medical institutions in those regions, and our market share, revenue and profitability could be adversely affected.

The tender processes can also create pricing pressure among substitute products or products that are perceived to be substitute products. Our sales volumes and profitability depend on our ability to successfully differentiate our products and price our bids in a manner that enables us to succeed in the centralized tender processes without compromising our profitability. If we are unable to differentiate our products or are otherwise not successful in winning bids in the centralized tender processes at profitable levels, our market share, results of operations and profitability could be adversely affected.

We may experience difficulties in our sales efforts as a result of pricing regulations or other policies that are intended to reduce healthcare costs, which could adversely affect our operations, revenue and profitability.

Prices of pharmaceutical products typically will decline over the life of the product due to factors such as the centralized procurement process or pricing regulation by the PRC government. In recent years, the PRC government increased its efforts to reduce overall healthcare costs by reforming the schemes of pricing regulation and statutory procurement processes for pharmaceutical products.

Currently, prices of pharmaceutical products are mainly determined by market competition through the centralized procurement process at the provincial level, without being subject to price ceilings previously set by the National Development and Reform Commission of the PRC (the “NDRC”) for drugs listed in national or provincial medical insurance catalogs before June 1, 2015. However, there is no assurance that such market-based pricing mechanism will result in higher product pricing. Competition from other manufacturers, particularly those offering similar products at more competitive prices, may force us to lower prices of our products upon commercialization. There is no guarantee that new policies on pharmaceutical pricing or changes in centralized procurement processes would not create any further downward pressure on the prices of our existing and future products. For example, the volume-based procurement scheme, or VBP scheme, is a major driver of the downward pricing pressure faced by pharmaceutical companies in China. See “Business—Pricing—Centralized Procurement Process and Volume-based Procurement” for details of the VBP scheme. As of the Latest Practicable Date, each drug class to which our generics belong had been included in the VBP scheme, and the substantial majority of our generics had participated in the VBP scheme. The inclusion of our products in VBP schemes allows us to sell our products in larger volumes; however, it also exerts downward pressure on the prices at which we sell our products to our distributors. Moreover, there may be discrepancies between the estimated

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procurement volumes set out in the tender documents and the actual procurement volumes. Consequently, there are uncertainties with respect to the impact of the implementation of the VBP schemes on the sales volume as well as the revenue of the winning products. Furthermore, there are uncertainties with respect to future coverage of VBP schemes. There can be no assurance that we may have additional drugs covered by such schemes in the future. If our competitors win the bid in such schemes while we fail to do so for our products with the same generic names, demands for our products may decrease and our revenue, profitability and market share could be adversely affected. Any such or future changes of policies, which we may not be able to predict or control, could create uncertainties that materially and adversely affect our product pricing, and accordingly, our revenue and profitability.

Our historical operational and financial performance may not be indicative of our future performance, and we may not be able to sustain similar growth in the future.

We experienced strong financial growth during the Track Record Period. However, our historical operational and financial performance should not be relied upon as an indication of our future performance. There are a wide array of factors that will affect our future growth and financial success, many of which are beyond our control. We cannot assure you that we will be able to maintain our growth at the same rate as we did in the past, or avoid any decline in our revenue or profitability in the future.

All material aspects of our operations are heavily regulated, and any failure to comply with applicable regulations could have a material adverse effect on our business, financial position, results of operations and prospects.

The pharmaceutical and medical device industries are subject to stringent regulation and supervision by government authorities in the PRC, the United States and other jurisdictions where we operate or intend to operate. These regulations govern virtually every aspect of our business operations, including product design and development, clinical trials, regulatory registration and approval, manufacturing, quality management, safety monitoring, marketing, sales and distribution.

Our manufacturing facilities and processes for both of our drugs and medical devices are subject to scheduled and unscheduled inspections by the NMPA and other comparable regulatory authorities to monitor our compliance with GMP and other applicable standards. There is no assurance that we will successfully pass these inspections or that our facilities will remain in compliance with rapidly evolving regulatory standards. In addition, we are subject to complex regulations affecting the commercialization of our products. There are specific laws and regulations that govern the procurement, prescription, and use of drugs and medical devices by hospitals and medical institutions, as well as the distribution of drugs to public medical institutions.

Any failure to comply with existing or future laws, regulations, or industry standards could subject us to severe administrative, civil or criminal sanctions. These may include, but are not limited to, the refusal to approve pending applications, withdrawal of existing approvals, license revocation, imposition of clinical holds, voluntary or mandatory product recalls, product seizures, suspension of production or distribution, injunctions, disgorgement of profits, and substantial fines. Furthermore, regulatory non-compliance could result in the disqualification of data submitted to regulatory authorities, termination of ongoing research, or a ban on future drug sales. Even if we successfully defend against regulatory actions, the proceedings could result in significant legal expenses, diversion of management's attention and severe damage to our reputation. Any of the foregoing could materially and adversely affect our business, financial position, results of operations and prospects.

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If we or our business partners fail to obtain, maintain or renew necessary licenses, permits and certificates for the development, production, promotion, and sale of our products, our business and results of operations could be adversely affected.

We are required to obtain, maintain and renew various licenses, permits and certificates to develop, manufacture, market, and sell our products. Our business partners, including suppliers, distributors and other third-party contractors, on whom we may rely to develop, manufacture, market, sell and distribute our products, may be subject to similar requirements. For details, see "Business—Legal and Compliance—Licenses, Permits and Certificates." We and our business partners may be subject to regular inspections, examinations, inquiries or audits by the regulatory authorities, and an adverse outcome may result in the loss or non-renewal of the relevant licenses, permits and certificates. Moreover, the criteria applied by government authorities in reviewing applications for, or renewals of, such licenses, permits and certificates may change from time to time, and there can be no assurance that we or our business partners will be able to meet new or enhanced criteria that may be imposed. Many of such licenses, permits and certificates are material to the operation of our business, and if we, or our business partners, fail to maintain or renew material licenses, permits and certificates, it could materially impair our ability to conduct our business. There is no assurance that we will be able to continue to maintain or renew our material licenses, permits and certificates in the future.

Any changes in the standards applied by government authorities in considering whether to renew or reassess our licenses, permits and certificates, as well as any enactment of new regulations that may restrict the conduct of our business, may decrease our revenue and increase our costs, which, in turn, could materially and adversely affect our profitability and prospects. Furthermore, if the interpretation or implementation of existing laws and regulations changes, or any new regulation comes into effect, so as to require us or our business partners to obtain any additional licenses, permits or certificates, there can be no assurances that we or our business partners will successfully obtain such permits, licenses or certificates.

Even if we obtain regulatory approval for the marketing of our products, we will remain subject to ongoing or additional regulatory obligations and continued oversight, which may result in significant additional expenses and expose us to liabilities.

Once approved, our products will be subject to ongoing or additional regulatory requirements imposed by the NMPA or other comparable regulatory authorities, including those relating to manufacturing, quality control, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing safety surveillance, and submissions of safety, efficacy and other post-marketing information and reports. We must also maintain continued compliance with the applicable GMP for production and GCP standards for any post-marketing clinical trials we conduct.

Any regulatory approvals that we receive may be subject to limitations on the indications for which the product may be marketed, which could adversely affect its commercial potential. In addition, such approvals may be conditional upon the performance of costly post-marketing testing and surveillance programs to monitor the safety and efficacy of our products. The NMPA or a comparable regulatory authority may also mandate a post-approval risk evaluation and mitigation strategy or a similar risk management program as a condition of approval, which could impose restrictions on use or distribution of our products.

Subsequent to approval, there could be discovery of previously unknown problems with our products, such as adverse events of unanticipated severity or frequency, issues with our manufacturing processes, or failure to comply with regulatory requirements. If any of the foregoing occurs, we may be subject to a range of enforcement actions or penalties, including: (i) restrictions on the manufacturing, marketing or distributions of the product; (ii) voluntary or mandatory product

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recalls, or withdrawal of the product from the market; (iii) fines, warning letters or holds on clinical trials; (iv) refusal by the NMPA or comparable regulatory authorities to approve pending applications or supplements to approved applications; (v) suspension or revocation of existing approvals; (vi) product seizure or detention, or refusal to permit the import or export of the product; and (vii) injunctions or the imposition of civil, administrative or criminal penalties.

In addition, we are subject to ongoing regulatory requirements for our day-to-day business operations, and compliance with these obligations requires us to continue allocating time, capital and management resources. Moreover, the regulatory environment in the PRC and other jurisdictions in which we operate is dynamic and evolving. As a result, we cannot predict the likelihood, nature or extent of governmental policies or regulations that may arise from future legislation or administrative actions. If we are unable to maintain regulatory compliance, or if we fail to adapt quickly to changes in existing requirements or the adoption of new policies, we may lose the regulatory approvals that we have obtained, and we may not be able to sustain profitability.

If we fail to achieve our expected product development milestones, it could adversely affect our business prospects.

Achieving product development milestones is critical to the success of our business, as these milestones directly influence our ability to successfully launch our products and meet our strategic goals. However, the successful implementation of our product development programs is subject to significant business, economic and competitive uncertainties and contingencies, including product development risks, the availability of sufficient capital, competition, the ability to obtain necessary regulatory approvals and permits, changes in regulations and government policies, and the overall growth trajectory in the relevant industries.

The actual timing for achieving our expected product development milestones could vary significantly from our current estimates due to a number of factors, many of which are beyond our control. There can be no assurance that our preclinical studies or clinical trials will be completed on schedule, or at all, or that we will make regulatory submissions or receive regulatory approvals as planned. Furthermore, we may face delays in establishing manufacturing capabilities or marketing arrangements necessary to commercialize our pharmaceutical products. If we fail to achieve one or more of these milestones as expected, we may be required to incur additional expenses and recognize impairment losses on our intangible assets, which could adversely affect our business prospects.

Additionally, we may explore out-licensing opportunities for our innovative drug assets. If future collaboration partners fail to meet the product development milestones for our out-licensed products, or fail to achieve the expected commercialization or sales targets for these products, our ability to receive milestone or royalty payments would be compromised. Such failure could also damage our reputation and diminish market confidence in our products, thereby materially and adversely affecting our business, financial position, results of operations and prospects.

Adverse events caused by our drug candidates could interrupt, delay or halt clinical trials, delay or prevent regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following any regulatory approval.

Adverse events caused by our drug candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the NMPA, FDA or other comparable regulatory authority, or could result in limitations or withdrawal following approvals. If results of our trials reveal a high and

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unacceptable severity or prevalence of adverse events, our trials could be suspended or terminated and the NMPA, FDA or other comparable regulatory authorities could order us to cease further development of, or deny approval of, our drug candidates.

Additionally, adverse events caused by our drug candidates, or caused by our drug candidates when used in combination with other drugs, could potentially cause significant negative consequences for our Company, including that: (i) regulatory authorities could delay or halt pending clinical trials; (ii) we may suspend, delay or alter development or marketing of the drug candidate; (iii) regulatory authorities may withdraw approvals or revoke licenses of an approved drug candidate, or we may determine to do so even if not required; (iv) regulatory authorities may require additional warnings on the label; (v) we may be required to develop a risk evaluation mitigation strategy for the drug candidate, or, if one is already in place, to incorporate additional requirements under the risk evaluation mitigation strategy, or to develop a similar strategy as required by a comparable regulatory authority; (vi) we may be required to conduct post-market studies; and (vii) we could be sued and held liable for harm caused to subjects or patients.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular drug candidate, and could significantly harm our business, results of operations and prospects.

We may not be able to identify, discover, develop or in-license new drug candidates, or to identify additional therapeutic opportunities for our drug candidates.

Besides the continued clinical testing, potential approvals and commercialization of our existing product candidates, the future success of our business depends in part upon our ability to identify, discover, develop, or in-license additional product candidates in order to continually expand our pipeline of innovative therapies. Our success in advancing several programs into clinical development does not guarantee that we will continue to successfully identify potential drug candidates as expected. In particular, the identification and validation of new targets in our focused therapeutic areas remain inherently uncertain, and some programs may present unique scientific, technical or manufacturing challenges. Product candidates that initially appear promising may later show side effects or other characteristics that make them unmarketable or unlikely to receive regulatory approvals.

In addition, we have pursued, and may continue to pursue, in-licensing or other collaboration opportunities with third parties in the discovery and development of potential drug candidates. For more details on our in-licensing arrangements, see “Business—Material Collaboration and Licensing Agreements.” There can be no assurance that such licensing and collaboration arrangements will deliver the intended results.

The data and information that we gather in our R&D process could be inaccurate or incomplete, which could affect the clinical development of our product candidates and harm our business, reputation, financial condition and results of operations.

We receive, collect, and analyze data and information from our preclinical studies and clinical trials. Because data in the pharmaceutical industry are often fragmented in origin, inconsistent in format, and incomplete, the overall quality of data collected or accessed in the industry is often subject to challenges, and the degree or amount of data which is knowingly or unknowingly absent or omitted can be material. Consequently, we may discover issues or errors in the capture, input, or analysis of such data during our data monitoring and auditing processes. Any such errors could compromise the integrity of our studies, delay our clinical development programs, or lead to the rejection of our regulatory applications, thereby materially and adversely affecting our business, prospects and reputation.

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We also manage and submit complex datasets to regulatory authorities to support our applications for regulatory approval. These submissions are governed by stringent data processing, validation and integrity regulations and policies. However, the interim, top-line or preliminary data from our clinical trials that we may release from time to time are subject to changes as more patient data become available and undergo audit and verification procedures. Such changes could expose us to liabilities if a court or government agency determines that our storage, handling, submission, delivery, or display of data was wrongful or erroneous. Our insurance coverage for clinical trials may be inadequate to fully cover such liabilities. Even if we successfully defend against such claims, the proceedings could result in substantial costs and the diversion of management’s time and resources. A successful claim brought against us that exceeds our insurance coverage could have a material adverse effect on our business, financial condition and results of operations.

Furthermore, we engage third-party CROs, site management organizations (“SMOs”) and other partners to monitor, manage and analyze data for our clinical trials. If these third parties fail to perform to our standards regarding data accuracy, completeness or security, or if they fail to comply with applicable regulatory requirements, the integrity of our clinical trials may be compromised as a result, and our reliance on these parties does not relieve us of our regulatory responsibilities. For details, see “—We engage third parties for certain aspects of our business. If these third parties fail to reliably, timely or cost-effectively provide us with their obligated services, our business could be adversely affected.”

If we fail to maintain, expand and optimize an effective distribution network for our pharmaceutical products, our sales and business prospects could be adversely affected.

Our ability to maintain and grow our sales depends on our ability to manage, expand and optimize distribution channels that ensure timely delivery of our products across China and/or in other jurisdictions in the future where market demand for our products is generated through our promotion and marketing activities, or otherwise. As of June 30, 2026, we had a distribution network of 678 distributors in China, which we rely on to distribute a substantial portion of our products.

All of our distributors are Independent Third Parties over whom we have limited control. We cannot assure you that they will at all times comply with our sales policies, or distribute our products in an effective and compliant manner. Non-compliance by any of our distributors may adversely affect the sales and distribution of our products. For example, if our distributors distribute our products outside their designated distribution areas as provided under their distribution agreements with us, the effectiveness of our distribution network could be adversely affected. If any of our distributors fails to distribute our products to their customers in a timely manner, overstock, or carries out actions which are inconsistent with our business strategy, it may adversely affect our future sales. The occurrence of any such event may materially and adversely affect our business, financial condition, and results of operations and prospects.

In line with industry practice, we typically enter into distribution agreements with our distributors for a term of one year, which requires renewal of these agreements to maintain our relationships with them. Our distributors might choose not to renew their agreements with us or otherwise terminate their business relationships with us for various reasons, including factors that limit the margins our distributors can obtain through the resale of our pharmaceutical products to hospitals, other medical institutions and retail pharmacies. In addition, our distributors typically do not sell our products exclusively, and they may favor the products of our competitors over our own, particularly if competing products offer higher margins or better commercial terms. If a significant number of our distributors cease or reduce their purchases of our products or fail to perform their obligations under the distribution agreements, our business, financial condition and results of operations may be materially and adversely affected.

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If our products cause, or are perceived to cause, severe side effects, our revenue and profitability could be adversely affected.

Our products may cause severe side effects as a result of a number of factors, many of which are outside our control. These factors include potential side effects not revealed in clinical studies, unusual but severe side effects in isolated cases, defective products not detected by our quality management system, or misuse of our products by end-users. Our products may also be perceived to cause severe side effects where a conclusive determination as to the cause of the severe side effects is not obtained or is unobtainable. In addition, our products may be perceived to cause severe side effects if other pharmaceutical companies’ products containing the same or similar APIs, raw materials or delivery technologies as our products are known or perceived to have caused severe side effects. Similarly, if one or more regulators in China or other jurisdictions, or an international institution, determines that products containing the same or similar pharmaceutical ingredients as ours cause or lead to severe side effects, this could also affect the perception of our products.

If our products cause, or are perceived to cause, severe side effects, we may face a number of consequences, including: (i) significant decrease in the demand for, and sales of, the affected products; (ii) recall or withdrawal of the affected products; (iii) revocation of regulatory approvals for the affected products or the associated production facilities; (iv) damage to our brand name and reputation; (v) stricter and more frequent regulatory inspections; (vi) removal of the affected products from medical insurance catalogs, including provincial lists of special medications for severe diseases; (vii) inability to participate in the centralized procurement processes; and (viii) exposure to lawsuits and regulatory investigation that may result in liabilities, fines or penalties. Any of these potential consequences could materially and adversely affect our revenue, profitability and business prospects.

Product liability claims could expose us to substantial costs and liabilities and adversely affect our operations, profitability and reputation.

We are exposed to product liability risks inherent in the development, manufacture, marketing, and sale of our products. Product liability claims may arise if any of our products are alleged or proven to be unsafe, ineffective, defective or contaminated, or if we are accused of having engaged in practices such as insufficient or improper labeling of products, inadequate warnings, or insufficient or misleading disclosures of side effects. There can be no assurance that we will not become subject to product liabilities claims or that we will be able to successfully defend ourselves against any such claims.

If a product liability claim is brought against us, regardless of its merit or outcome, it could strain our financial resources and divert the time and attention of our management from our core operations. Such claims could also result in severe reputational damage, leading to a loss of brand equity, decreased demand for our products, and inability to commercialize our product candidates. If we are unable to successfully defend against such claims and our products are found to be defective or to have caused harm, we may be held liable for significant damages related to physical injury, death, or other losses. In addition to civil liability, we may face criminal charges and severe administrative penalties, including the revocation of our business or manufacturing licenses. We may also be required to initiate product recalls, suspend production, or cease sales of the affected products altogether. Furthermore, as we expand our global footprint, we may face heightened risks in jurisdictions with more litigious environments or more onerous product liability regimes, such as in the United States and Europe.

We currently do not maintain any product liability insurance, as PRC laws and regulations do not mandate insurance coverage for product liability claims. Consequently, we may be required to pay substantial damages from our internal resources, which could hinder the commercialization of

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our products and have a material adverse effect on our financial condition and results of operations. For details, see “—Our insurance coverage is limited. If we experience uninsured losses, it could adversely affect our financial condition and results of operations.”

Negative results from off-label use of our products could materially and adversely affect our business, reputation, brand name, and results of operations and expose us to liability claims.

Products distributed or sold in the pharmaceutical market may be subject to off-label drug use, which involves prescribing a product for an indication, dosage or dosage form that is not in compliance with regulatory approved usage and labeling. The NMPA and other comparable regulatory authorities actively enforce laws and regulations prohibiting pharmaceutical companies from promoting or marketing products for off-label use. We cannot control the prescription practices of physicians. Therefore, there remains the risk that our products are subject to off-label drug use and are prescribed in a patient population, dosage or dosage form that has not been approved by regulatory authorities, which may render our products less effective or ineffective or result in severe adverse drug reactions. Any of these occurrences, even if strictly from off-label use, can generate negative publicity and significantly damage our business, reputation and brand name, and expose us to product liability claims, administrative penalties and regulatory investigations. These occurrences may also cause a delay in the progress of our clinical studies, particularly those aimed at expanding the approved indications of our products, and may ultimately result in the denial of regulatory approval, which could, in turn, adversely affect our business and results of operations.

If we are unable to obtain and maintain patent protection for our products and product candidates through intellectual property rights, or if the scope of such intellectual property rights obtained is not sufficiently broad, our competitors could compete against us more effectively, which may have a material adverse impact on our business and results of operations.

Our success depends in large part on our ability to protect our proprietary technology, products and product candidates from competition by obtaining, maintaining and enforcing our intellectual property rights, including patent rights, and to maintain adequate legal protection for our technology and products in the PRC and worldwide. We seek to protect the technology, products and product candidates that we consider commercially important by filing patent applications in the PRC and worldwide, relying on trade secrets or medical regulatory protection or employing a combination of these methods. This process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner.

It is also possible that we may fail to timely identify patentable aspects of our R&D output to obtain patent protection, and there is no assurance that any of our pending patent applications will lead to issued patents, or that such patents, if issued, will provide us with adequate proprietary protection or competitive advantages. We rely on non-disclosure and confidentiality agreements or such provisions in our relevant agreements with parties who have access to confidential or patentable aspects of our R&D output, such as our employees, consultants, advisors and other third parties. However, these measures may not be effective, and any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

Filing, prosecuting, maintaining and defending patents on products and product candidates in all countries throughout the world could be time-consuming and expensive. In addition, the patentability requirements across countries and regions vary and the laws of different countries or regions do not provide patent protection to the same extent. Therefore, our patent applications may not be granted in all countries and regions, and the scope and strength of issued patents can vary

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globally. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries, or from selling or importing medical products made using our inventions in and into certain jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to certain jurisdictions where we have patent protection but where enforcement rights are not as strong as those in certain other countries. These products may compete with our products and product candidates and our patent rights or other intellectual property rights may not be effective or adequate to prevent them from competing.

Furthermore, there are a number of factors that could cause our existing patents or other intellectual property to become invalid or unenforceable, including known or unknown prior art, deficiencies in patent applications and lack of originality in the underlying technologies. Publications of discoveries in the scientific literature often lag behind the actual discoveries. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications or that we were the first to file for patent protection of such inventions. If the patents relevant to our products or product candidates were to be declared invalid or unenforceable, it could have an adverse impact on the sales volume and pricing levels for our products and our ability to successfully commercialize the product candidates.

Patent terms may not be sufficient to effectively protect our products and business.

The life of a patent and the protection it affords is limited. Moreover, given the amount of time required for the clinical development and regulatory review, patents protecting our product candidates might expire before or shortly after they are commercialized. As a result, our patents and patent applications may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

In the PRC, the patent law has established a patent term extension mechanism for eligible invention patents. Under this regime, to compensate for the time used by the regulatory review and approval process, the patent administration may, at the request of the patent holder, grant a patent term extension for invention patents of new drugs approved for marketing in China. The compensation period may not exceed five years, and the total valid patent term shall not exceed 14 years after the marketing approval of the new drugs. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements.

The loss of patent protection or regulatory exclusivity for pharmaceutical products may open such products to competition from generic or biosimilar substitutes that are typically priced significantly lower than the originator products, which typically adversely affects the market share and prices of the originator products. For example, the compound invention patent, which covers the active ingredient for one of our major marketed drugs, XinLiTan, expired in July 2026. It is expected over the next several years to face intensified competition, pricing pressure, and loss of market share, following the introduction of lower-priced generics. For details on the expiry dates of patents considered material to our business, see “Appendix VI—Statutory and General Information—B. Further Information About our Business—2. Intellectual Property Rights of our Group—(b) Patents.”

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We may be subject to intellectual property infringement claims, which could divert our management's attention, expose us to substantial liability, harm our reputation, limit our R&D or other business activities and impair our ability to sell our products or commercialize our product candidates.

We have been, and may from time to time become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our technology and any products or product candidates we may develop. As our industry expands and more patents are issued, the risk increases that our products or product candidates or technologies that we develop may be subject to claims of infringement of the patent rights of third parties.

Third parties may assert infringement claims against us based on patents or other proprietary rights that they currently hold, have license to, or may be granted in the future, regardless of their merit. The risk of being subject to intellectual property infringement claims will increase as we continue to expand our operations and product offerings. Additionally, as patent applications can take many years to issue, there may be pending patent applications which might eventually lead to issued patents which our products or product candidates could inadvertently infringe. Moreover, there may be existing patents that we are not aware of or that we have incorrectly concluded are invalid or not infringed by our activities. As such, we may be unable to determine whether any of our products, product candidates, processes and other related matters infringe upon the intellectual property rights of others.

We have received, and may from time to time receive, notices that claim our technologies or certain other aspects of our business have infringed, misappropriated or misused third parties' intellectual property rights. Whether or not third-party intellectual property claims have merit, there is no assurance that a court would find in our favor on questions of infringement, validity, enforceability or priority. If we are found to have infringed on a third party's intellectual property, and we are unsuccessful in demonstrating that such patents or other intellectual property rights are invalid or unenforceable, we could be required to: (i) obtain royalty-bearing licenses from such third party, which may not be available on commercially reasonable terms, if at all; (ii) acquire any necessary licenses from third parties, which could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and requiring us to make substantial licensing and royalty payments; (iii) defend litigation, arbitration, or administrative proceedings; (iv) reformulate our products or product candidates so that they do not infringe the intellectual property rights of others, which may not be technically feasible or could be costly and time-consuming; (v) cease developing, manufacturing and commercializing the infringing products, product candidates or technologies due to court-imposed injunctive relief; or (vi) pay such third party significant monetary damages, if we are found to have willfully infringed a patent or other intellectual property right.

Furthermore, claims that we or our employees have misappropriated the confidential information or trade secrets of third parties could have a material adverse effect on our business, financial condition, results of operations, and prospects. Certain of our employees were previously employed at medical institutions and pharmaceutical companies, including our competitors or potential competitors. As such, we may be subject to claims that we or our employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of their former employers. Litigations or administrative proceedings may be necessary to defend against these claims, and even if we are successful in these litigations or administrative proceedings, such litigations and proceedings may be costly and could result in a substantial diversion of management resources.

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If we fail to comply with our obligations under our existing intellectual property licensing agreements or under any future intellectual property licenses, or otherwise experience disruptions to our business relationships with our current or future licensors, we could lose intellectual property rights that are important to our business.

We are party to a few in-licensing agreements, pursuant to which we have been granted by third parties rights to, among other things, develop, manufacture and commercialize licensed pharmaceutical products in designated regions. Our current license agreements impose, and we expect that future licenses may continue to impose, specified royalty payments and other obligations on us. For more details on our in-licensing arrangements, see “Business—Material Collaboration and Licensing Agreements.”

Current or any future licensors might conclude that we have materially breached our license agreements with them and might therefore terminate the license agreements, thereby impacting our ability to market and sell the relevant pharmaceutical products. If these in-licenses are terminated, or if the underlying intellectual property fails to provide the intended exclusivity, our competitors could market and sell the same products or products similar to our licensed products. This could adversely affect our results of operations and business prospects.

In addition, we may enter into out-licensing arrangements for our innovative drug assets, pursuant to which we may grant third parties rights to develop, manufacture and commercialize certain of our licensed products in designated regions. If we are unable to obtain ownership or licensing of certain intellectual property generated through these collaborations, our business and results of operations could be adversely affected.

Intellectual property licensing agreements are inherently complex, and certain provisions in such agreements may be susceptible to multiple interpretations. As a result, disputes may arise with our licensing partners regarding, among other things, the scope of ownership or license rights granted, the assignment or sublicensing of rights, and the ownership of inventions and know-how resulting from joint development. Any such disputes, or disagreements regarding the interpretation of contractual provisions, could limit the scope of the rights we expected to receive, increase our financial or other obligations, or delay the development or commercialization of our products. We did not experience any disputes or material claims in relation to our intellectual property licensing agreements during the Track Record Period. However, if any such disputes arise in the future and we are unable to resolve disputes in a timely manner or maintain our licensing arrangements on commercially acceptable terms, our business, financial condition, results of operations and prospects could be adversely affected.

Illegal and parallel imports and counterfeit products could negatively affect our sales and damage our reputation and the brand names of our products.

The illegal import of similar or competing products from countries where government price controls or market dynamics result in lower prices may adversely affect the demand for our products and, in turn, our sales and profitability in the PRC and other jurisdictions where we operate or plan to commercialize our product candidates. While unapproved foreign imports are illegal under current PRC laws and the laws of many other countries, such illegal imports may continue to occur or even increase, particularly where patient demand for these lower-priced imports remains strong. Furthermore, cross-border imports from lower-priced markets into higher-priced markets (*i.e.*, parallel imports) could negatively impact sales of our products and exert downward pressure on our pricing in key markets. In addition, regulatory authorities may implement measures to expand consumer access to lower-priced substitutes of our products or competing products from outside the PRC or other countries where we operate. Any future legislation, regulations or policy shifts that facilitate the access to lower-priced products from foreign jurisdictions could have a material adverse effect on our business, financial condition and results of operations.

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In addition, certain products distributed or sold in the PRC and international markets may be manufactured without proper licenses or approvals, or may be fraudulently mislabeled with respect to their content, usage or manufacturers. These counterfeit pharmaceutical products often mimic the appearance of authentic products but are typically sold at significantly lower prices, which may erode demand for our legitimate products. Moreover, counterfeit products may lack the precise chemical composition of our products, which may make them less effective, entirely ineffective or more likely to cause severe adverse effects. The administration of such substandard products could expose us to negative publicity, reputational damage, fines and other administrative penalties, and may even result in product liability litigation against us, even if the alleged injury was caused by a counterfeit product. The presence of counterfeit products, products of inferior quality and other unqualified products may also reinforce the negative perceptions of our industry as a whole and may damage our reputation and brand name, which could materially and adversely affect our business, financial condition, results of operations and prospects.

If we suffer substantial disruption to any of our manufacturing facilities or encounter operational failures in our manufacturing processes, our business and results of operations could be adversely affected.

We manufacture all of our products at our own manufacturing facilities. The continued operation of these facilities and the safety of our production may be substantially interrupted and adversely affected by a number of factors, many of which are beyond our control. These include natural disasters, health epidemics, power outages, fuel shortages, mechanical breakdowns, and acts of war or terrorism. We are also subject to the risks regarding the maintenance of necessary licenses, permits or certificates, as well as changes in government planning or zoning requirements that could affect the land used for our facilities.

If the operation of any of our manufacturing facilities is significantly disrupted, we may not be able to repair or replace essential equipment or inventories at such facilities, or secure alternative production sites or third-party contractors in a timely and cost-effective manner, or at all. We do not maintain business interruption insurance, and our existing insurance coverage may not be sufficient to fully cover our losses in the event of a significant disruption to our manufacturing facilities.

Furthermore, we may encounter operational failures during our manufacturing processes due to equipment malfunctions, deviations from established protocols and standard operating procedures, or physical capacity limitations that constrain continuous supply. Any such disruptions or operational failures could prevent us from fulfilling contractual obligations or meeting market demand for our products, which would materially and adversely affect our business, revenue and profitability.

If we fail to increase our production capacity or upgrade our existing production facilities in response to increasing demand for our products, our business prospects could be adversely affected.

As part of our strategies, we intend to expand and upgrade our production facilities to support our business growth. See “Business—Our Strategies” for more details. However, our ability to successfully implement such plan is subject to a number of risks and uncertainties, including our ability to obtain the requisite licenses, permits and approvals for the operation of any new production lines, delays in equipment procurement, as well as our ability to timely recruit sufficient qualified staff to support the expansion of our production capacity. Consequently, there can be no assurance that we will be able to increase our production capacity or upgrade our existing production facilities in the manner we contemplate. If we fail to do so, we may not be able to capture the potential growth in demand for our products or successfully commercialize additional products, which could adversely affect our results of operations and business prospects. Moreover, our plans to upgrade our production facilities require significant capital investment, and the actual

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costs of such plan may exceed our initial estimates, which could adversely affect the return on our expenditure. The implementation of our plans may also increase our operating costs, such as higher staff costs, depreciation and utility expenses, which may adversely affect our financial condition and results of operations.

Failure to maintain optimal inventory levels could increase our operating costs or lead to unfulfilled customer orders, either of which could have a material adverse effect on our business and results of operations.

As of December 31, 2023, 2024, 2025, and June 30, 2026, our inventories amounted to RMB490.9 million, RMB506.8 million, RMB548.2 million, and RMB567.7 million, respectively. We seek to maintain optimal inventory levels to fulfill orders from our extensive distribution network and meet customer demand. However, we are exposed to inventory risk as a result of rapid changes in product lifecycles, evolving clinical needs, uncertainties in product developments and launches, as well as the volatility of the global economic environment. Furthermore, demand for our products could change significantly between the time when the products receive regulatory approval and the time they are ready for sale and delivery. When we begin to sell a new product, it is particularly difficult to forecast demand accurately.

There can be no assurance that we can accurately predict customer demand or market trends, or that we will effectively avoid over-stocking or under-stocking our products. On the one hand, inventory levels in excess of demand may result in inventory write-downs, expiration of products with limited shelf lives, and increased inventory holding costs, and could have a negative effect on our liquidity and cash flows. On the other hand, if we underestimate demand, we may experience inventory shortages, which may, in turn, result in unfulfilled customer orders, loss of immediate sales revenue, and long-term damage to our customer relationships and market reputation. There can be no assurance that we will be able to maintain proper inventory levels at all times, and any such failure may have a material adverse effect on our business and results of operations.

We depend on the supply of certain raw materials. Such supplies may not be available to us in acceptable quality or on commercially acceptable terms or at all, which could adversely affect our sales volume and margins for the relevant product.

Purchase of raw materials accounted for a significant portion of our total cost of sales during the Track Record Period. To manufacture our products, we must obtain sufficient quantities of high-quality raw materials at commercially acceptable prices and in a timely manner. During the Track Record Period, we sourced high-grade chemical intermediates and APIs from qualified suppliers. For more details, see “Business—Our Suppliers.” We typically do not enter into long-term supply agreements with raw material suppliers and, as a result, we are vulnerable to supply shortages and fluctuations in market prices.

As we continue to develop our manufacturing process and scale our production capacity, there is no assurance that we will be able to, at all times, procure raw materials we need in adequate amount or on commercially reasonable terms, in a timely manner, or at all. Any potential interruption or shortage could delay the production and delivery schedules of the relevant products, which may result in the loss of customers and revenue.

In addition, the market prices of raw materials may be subject to significant fluctuations due to various factors. We cannot assure you that we would be able to pass on any increase in raw material costs to our customers, and any substantial fluctuation in market prices of raw materials may materially increase our costs and impact our profitability. Potential disruptions to the supply

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chain, such as natural disasters, geopolitical tensions, transportation issues, or other unforeseen events, could further exacerbate these challenges and result in delays, increased costs, or interruptions in our production processes.

If we fail to retain our key senior management members or to attract, retain and train qualified personnel, our business prospects could be adversely affected.

Our future success depends heavily upon the continued services of our senior management members, key R&D personnel and core sales and marketing personnel. In particular, the industry experience, management expertise and strategic vision of our Directors and our senior management are instrumental to our operations.

We have employment agreements with each of our senior management members, key R&D personnel and core sales and marketing personnel. However, these agreements do not prevent them from terminating their employment with us at any time. Furthermore, we do not maintain any key person insurance for any of our Directors, senior management members or other key personnel. If we lose the services of any key personnel, we may be unable to recruit a suitably qualified replacement in a timely manner or at all, and we may incur significant additional expenses to recruit and train new personnel. In addition, if any of our key personnel joins a competitor or forms a competing business, we may lose crucial know-how, trade secrets and customer relationships. Any of these events could disrupt our operations, materially and adversely affecting our results of operations and business prospects.

Furthermore, as we expect to continue expanding our operations and product portfolio, our success will depend on our ability to recruit, retain and train qualified personnel in R&D, manufacturing, quality management, sales and marketing, and other key business functions. If we are unable to attract, motivate, train and retain these key personnel required to achieve our business objectives, our business prospects could be adversely affected.

We engage third parties for certain aspects of our business. If these third parties fail to reliably, timely or cost-effectively provide us with their obligated services, our business could be adversely affected.

We rely on third parties, such as qualified medical institutions, CROs and SMOs, in certain aspects of our business, including the design and conduct of clinical trials for our product candidates as well as commercialization of our products or product candidates in specific regions. Our business will be adversely affected if business or economic conditions or future developments in applicable laws and regulations negatively impact the operations of these third parties and, consequently, reduce their ability or willingness to provide services to us.

If these third parties, whom we do not control, do not successfully fulfill their contractual duties or regulatory obligations or meet expected deadlines, or if our collaboration partners do not have the ability or the resources to successfully complete their objectives, or choose not to continue their relationship with us, our development and commercialization efforts could be delayed, suspended or terminated. In addition, if the quality or accuracy of the data we obtain from these third parties is compromised due to their failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical activities could be delayed and we may not be able to obtain regulatory approvals for our product candidates.

Our acquisitions, collaborations, licensing arrangements, joint ventures, strategic alliances, partnerships and other strategic investments or arrangements may fail to produce the anticipated benefits and adversely affect our operations.

We may pursue growth through acquisitions of technology, assets or other businesses that may enable us to enhance our technologies and capabilities. We may also pursue opportunities for collaborations, licensing arrangements, joint ventures, strategic alliances, partnerships or other

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strategic investments or arrangements that we believe will advance our business. However, identifying, proposing, negotiating and implementing these opportunities may be a lengthy and complex process. We may face competition for such opportunities from competitors with substantially greater financial, marketing, technological or other resources. As a result, we may not be able to identify, secure, or complete any such acquisitions or strategic investments or arrangements in a timely manner, on acceptable terms, or at all.

To the extent that we successfully complete acquisitions or enter into strategic investments or arrangements, the subsequent management and integration of the acquired business, brands or product portfolio, as well as the execution of such strategic investments or arrangements, may be complex and could disrupt our operations, result in significant expenses, reduce our profitability, or divert management's attention from our existing business. In addition, valuations supporting our acquisitions and strategic investments may change rapidly due to market or business development, and we may be required to record impairment losses on our investments or acquired assets, which could materially and adversely affect our business, financial condition and results of operations. Moreover, the success of these acquisitions, strategic investments or arrangements depends on the cooperation and performance of our partners, collaborators, or other counterparties. These parties may fail to perform their obligations, meet our expectations or cooperate with us satisfactorily for various reasons, which could subject us to potential risks. Any such acquisitions, strategic investments or arrangements may also require consents, approval, waiver, participation or other forms of participation by third parties, including regulators, government authorities, licensing partners, shareholders or stakeholders. There is no assurance that such parties will be cooperative or provide the necessary consents or approvals, which may delay or prevent us from completing the relevant transactions or arrangements. As a result of any of the foregoing, we may not realize the anticipated benefits of our acquisitions or strategic investments or arrangements, including any anticipated synergies, cost savings or operational efficiencies, within the expected timeframe, or at all.

We may grow our business through acquisitions or investments in the future, but we may fail to identify suitable targets, complete such acquisitions or investments, or realize the intended benefits.

As part of our growth strategy, we may from time to time evaluate and pursue selective strategic collaborations, or investments in suitable targets, including pharmaceutical and biotechnology companies. We may also seek to license or acquire complementary products, intellectual property rights, technologies or businesses to execute our business plan. However, our ability to successfully identify, execute and realize the intended benefits of any acquisition or investment is subject to a number of risks and uncertainties. We may not be able to identify suitable targets or may face intense competition for attractive opportunities, which may make it difficult to consummate acquisitions or investments on commercially acceptable terms, or at all. Furthermore, even if suitable targets are identified, we may lack access to necessary financing on acceptable terms. The pursuit of such transactions could also result in increased operating expenses, significant cash requirements, the incurrence of additional indebtedness, or the exposure to contingent liabilities.

Negative publicity concerning our industry, us, or our management, employees, affiliates or business partners may adversely affect our brand, reputation and business prospects.

Our brand is important to attracting and retaining customers, business partners and collaborators, and our success depends significantly on our ability to maintain and enhance our brand image and reputation. Our ability to do so depends largely on the success of our efforts to deliver reliable products, the effectiveness of our marketing activities, and our ability to secure, maintain, and defend our rights to use our brand name and trade names.

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There can be no assurance that we will be able to maintain a positive reputation or brand name in the future. Our reputation and brand name may be adversely affected by a number of factors, many of which are beyond our control, including: (i) negative publicity associated with our industry or our products, including with respect to their efficacy or side effects, whether founded or not; (ii) the effects of counterfeit products purporting to be our products; (iii) any misconduct, or allegations thereof, by our management, employees, affiliates and business partners, whether authorized by us or not; and (iv) lawsuits and regulatory investigations against us, our management, employees, affiliates or business partners or otherwise relating to our products or industry.

Our brand value also depends on our ability to maintain a positive customer perception of our corporate integrity and culture. Any negative publicity concerning our industry, us, or our management, employees, affiliates or business partners, or any entity authorized to use our brand name or otherwise associated with us, even if untrue, could materially and adversely affect our brand, reputation, and business prospects.

In addition, social media practices in our industry continue to evolve, and the regulatory framework governing such use may be subject to interpretation and change. As a result, we may face uncertainty and risk of non-compliance with regulations applicable to our business. For example, patients may use social media channels to comment on the effectiveness of a pharmaceutical product or report an alleged adverse event. We may not be able to closely monitor all such posts or comments, and therefore we may not be able to fully comply with applicable pharmacovigilance and adverse event reporting obligations. Furthermore, regulatory restrictions on product promotion may restrict our ability to respond to or correct inaccurate commentary on our product candidates. We also face risks arising from the inappropriate disclosure of sensitive information, as well as negative or inaccurate posts or comments about us on social media platforms. If we are unable to effectively manage these risks, or if we fail to comply with applicable regulations regarding social media usage, we may incur liability, face regulatory actions, or suffer material harms to our business.

We may become involved in litigation, arbitration, administrative or other legal proceedings, disputes or claims, which may divert our management's attention, result in costs and liabilities, damage our reputation, and adversely affect our business operations.

We have been, and may from time to time become, involved in litigation, arbitration, administrative or other legal proceedings, disputes or claims arising in the ordinary course of business with our customers, suppliers, business partners, minority shareholders of our non-wholly owned subsidiaries, joint venture partners, employees, competitors, regulatory agencies, or other parties in respect of contractual, commercial, labor, intellectual property, or other matters. Such involvement can distract our management's attention and consume significant time and resources. Furthermore, legal proceedings, disputes or claims which are initially deemed not material may escalate and become material due to various factors, including the discovery of new facts, changes in the legal grounds for the claims, the likelihood of winning or losing, the amount of damages seeking to be recovered, and the parties concerned.

Negative publicity arising from litigation, arbitration, administrative or other legal proceedings, disputes or claims may damage our reputation and adversely affect the public perception of our brand and products. In addition, if any adverse judgement, decision, or arbitration award is rendered against us, we could be required to pay significant monetary damages, assume other liabilities, or suspend certain business activities. Consequently, our business, financial condition and results of operations may be materially and adversely affected.

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We are subject to credit risk in relation to our trade and bills receivables.

We extend credit to certain customers. As of December 31, 2023, 2024, 2025, and June 30, 2026, our trade and bills receivables, net impairment, amounted to RMB467.4 million, RMB516.8 million, RMB721.4 million, and RMB807.5 million, respectively. Our ability to collect these receivables depends heavily on the financial condition and creditworthiness of our customers and the overall economic environment in which they operate. There is no assurance that we will be able to collect all or any of our trade and bills receivables in a timely manner, or at all.

We assess the recoverability of our trade receivables and record allowance for impairment based on our estimates of expected credit losses. As of December 31, 2023, 2024, 2025, and June 30, 2026, we recorded allowance for impairment of trade and bills receivables of RMB19.4 million, RMB24.9 million, RMB28.7 million, and RMB27.0 million, respectively. However, our estimate and judgment regarding the recoverability of our trade and bills receivable may not accurately reflect actual future events. If our customers experience unexpected situations, such as financial difficulties or a deterioration in their creditworthiness, we may face significant challenges in collecting payments, and enforcing our rights and collecting outstanding payments through legal proceedings can be time-consuming, costly and uncertain.

If we are unable to collect our trade and bills receivables as they become due, we may be required to record significantly higher provisions for impairment or write off such receivables entirely. This would directly reduce our profitability and could constrain our working capital and cash flows, thereby materially and adversely affecting our financial condition and ability to fund our operations.

We may incur impairment losses for goodwill and other intangible assets, which could adversely affect our results of operations.

We recorded goodwill of RMB10.9 million, RMB10.9 million, RMB219.5 million, and RMB219.5 million as of December 31, 2023, 2024, 2025, and June 30, 2026, respectively. In addition, as of December 31, 2023, 2024, 2025, and June 30, 2026, we had other intangible assets with net carrying amount of RMB2,492.4 million, RMB2,694.7 million, RMB3,138.5 million, and RMB3,359.6 million, respectively, which comprised primarily (i) deferred development costs, (ii) licenses, representing royalty fees arising from our in-license arrangements, and (iii) non-patent technology. In 2023, 2024, 2025, and the six months ended June 30, 2026, we recognized impairment losses for goodwill and other intangible assets of RMB50.6 million, RMB157.3 million, RMB151.1 million, and nil, respectively. For details, see Notes 16 and 17 of the Accountants’ Report in Appendix I to this document. Expenditure incurred on projects to develop new products is capitalized and deferred only when we can demonstrate the technical feasibility of completing the projects so that our new products will be available for use or sale, among other factors.

Goodwill is tested for impairment annually, or more frequently if events or changes in circumstances indicate that it may be impaired. Intangible assets with finite useful lives are assessed for impairment whenever there is an indication that the assets may be impaired, while intangible assets with indefinite useful lives are tested for impairment annually and at other times when such an indicator exists. Accordingly, assessing whether goodwill and other intangible assets are impaired requires an estimate of the recoverable amount of these assets, which is based on certain assumptions made by our management. If any of these assumptions does not materialize, or if the performance of our business is not consistent with such assumptions, the carrying amount of the intangible assets may exceed its recoverable amount, and our intangible assets may accordingly be impaired. As a result, we may be required to have a significant write-off of our intangible assets and record a significant impairment loss. The impairment of intangible assets could have a material adverse effect on our business, financial condition and results of operations.

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Our financial condition and results of operations may be adversely affected by fair value changes in our financial assets at fair value through profit or loss.

During the Track Record Period, we held certain financial assets at fair value through profit or loss, which primarily consisted of investments in structured deposits, wealth management products and unlisted equity. As of December 31, 2023, 2024, 2025, and June 30, 2026, our financial assets at fair value through profit or loss amounted to RMB994.6 million, RMB1,767.1 million, RMB1,543.3 million, and RMB1,395.8 million, respectively. Our financial assets at fair value through profit or loss are measured at fair value, with changes in their fair value recognized in our profit or loss. As a result, any volatility in the fair value of these assets directly impact our results of operations. In 2023, 2024, 2025, and the six months ended June 30, 2026, we recognized net fair value gain on financial assets at fair value through profit or loss of RMB8.1 million, RMB14.5 million, RMB36.7 million, and RMB9.7 million, respectively. There is no assurance that we will continue to recognize fair value gains in the future. Any significant fair value losses recognized could materially and adversely affect our financial condition and results of operations.

If our preferential tax treatments and government grants become unavailable or otherwise change or terminate, it could adversely affect our profitability.

Historically, we have benefited from a number of preferential tax treatments and tax allowances. During the Track Record Period, our Company and certain of our PRC subsidiaries were recognized as “High and New Technology Enterprises” (the “HNTEs”) and are eligible for a preferential income tax rate of 15%, compared to the statutory standard 25% income tax rate generally applicable to PRC resident enterprises.

The preferential tax treatments and tax allowances applicable to us may be changed, terminated, or otherwise become unavailable due to many factors, including changes in policies or administrative decisions by relevant government authorities. Our post-tax profitability may be adversely affected as a result of one or more of these or other factors. For example, HNTE qualifications are subject to review by the relevant PRC tax authority every three years. There is no guarantee that we or our PRC subsidiaries will be able to renew these qualifications. If we fail to do so, the affected subsidiaries will no longer enjoy the 15% preferential income tax rate, and will be subject to the 25% income tax rate, unless eligible for other preferential tax treatments, which would increase our tax liabilities and reduce our net profits.

Furthermore, in 2023, 2024, 2025, and the six months ended June 30, 2026, we recognized government grants as other income and gains in the amount of RMB79.2 million, RMB53.9 million, RMB102.9 million, and RMB15.3 million, respectively. Government grants are non-recurring in nature and subject to the sole discretion of the relevant government authorities. The availability, timing, and amount of such grants depend on various factors, including government policies and the availability of funds, which are beyond our control.

There can be no assurance that we would continue to enjoy these preferential tax treatments and government grants at the historical levels, or at all. Any change, suspension or discontinuation of these preferential tax treatment and government grants to us could adversely affect our financial condition, results of operations and cash flows.

Failure to obtain sufficient funding on terms acceptable to us, or at all, could adversely affect our business prospects.

The implementation of our strategies and our general business operations have ongoing funding requirements that may increase over time, which may require us to rely, in part, on external financing sources. However, our ability to obtain external financing on commercially reasonable terms, or at all, will depend on a number of factors, many of which are beyond our control, including our financial condition, results of operations and cash flows, economic condition in the PRC and globally, industry and competitive dynamics, interest rates, prevailing conditions in the

RISK FACTORS

credit markets and government policies on lending. If we cannot obtain sufficient funding on commercially acceptable terms to implement our strategies and business plans, we could be required to revise, delay or scale back our strategies and business plans, which could adversely affect our business prospects.

We may seek additional funding through a combination of equity and debt financings. To the extent that we raise additional capital through the issuance of equity or convertible debt securities, the beneficial ownership interest of existing shareholders could be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of our existing shareholders. The incurrence of additional indebtedness or the issuance of certain equity securities could result in increased fixed payment obligations and additional restrictive covenants, such as incurring additional debt, making capital expenditures, or declaring dividends, which could constrain our operations and affect the execution of our strategies and business plans.

Our insurance coverage is limited. If we experience uninsured losses, it could adversely affect our financial condition and results of operations.

We maintain insurance coverage that we consider to be customary for our industry in the PRC. However, this coverage is limited and does not cover all risks associated with our business operations. We do not maintain any product liability insurance, business interruption insurance or key person insurance. If we experience disruptions to our business, we might incur substantial costs and suffer a diversion of resources, and any related losses may not be fully covered by insurance, or at all. For details of our insurance coverage, see “Business—Insurance.”

In addition, there are certain types of losses, such as losses from war, acts of terrorism, epidemics, public security hazards, earthquakes, typhoons, flooding and other natural disasters, for which we cannot obtain insurance at a reasonable cost or at all. If an uninsured loss or a loss exceeding our insurance coverage occurs, we could suffer significant financial losses, lose all or a portion of our production capacity, as well as future revenue anticipated to be derived from the manufacturing activities conducted at the affected facilities. If we experience uninsured losses or losses in exceeding our insurance coverage, it could adversely affect our financial condition and results of operations.

An occurrence of a natural disaster, widespread health epidemic or other outbreaks could have a material adverse effect on our business, financial condition and results of operations.

Our business could be materially and adversely affected by natural disasters, such as adverse weather conditions, natural disasters, the outbreak of a widespread health epidemic, such as COVID-19 pandemic, swine flu, avian influenza, Ebola, and Zika, or other catastrophic or disruptive events, including wars, acts of terrorism, environmental accidents, power shortage or communication interruptions. The occurrence of any such events in the PRC or elsewhere in the world could materially disrupt our business and operations. In particular, these events could significantly impact our industry and cause a temporary suspension or closure of the facilities used for our R&D, manufacturing and operations, which would severely disrupt our product development and manufacturing process and overall business operations and have a material adverse effect on our business, financial condition and results of operations.

RISKS RELATED TO DOING BUSINESS IN THE JURISDICTIONS WHERE WE OPERATE

Approvals of or filings with PRC government authorities may be required in connection with our future [REDACTED].

PRC laws and regulations in relation to overseas issuance and listing of shares may be subject to change. Under current regulations, we are required to file with or report to the CSRC and may in the future be required to file with or report to other PRC governmental authorities for our capital

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raising activities. For detailed discussion on the PRC laws regulating overseas securities offering, see “Regulatory Overview—PRC Laws and Regulations—Regulations on Overseas Securities Offering and Listing by Domestic Enterprises.” Any failure to complete or delay in completing such filing or reporting procedures for our financing activities could subject us to sanctions by the CSRC or other PRC regulatory authorities. These regulatory authorities may impose fines and penalties on us, limit our ability to pay dividends outside of the PRC, limit our operating activities in the PRC, delay or restrict the repatriation of the net proceeds from the capital raising activities into the PRC, or take other actions that could materially and adversely affect our business, financial condition, results of operations, and prospects, as well as the [REDACTED] of our H Shares.

We are exposed to specific risks of conducting our business and operations in international markets.

We sell APIs and intermediates to overseas markets. In addition, we engage in other forms of collaboration worldwide, including clinical trials. As we strategically expand our global footprint, we may engage in additional global multi-regional clinical trials and explore out-licensing collaborations with overseas partners for our innovative drug assets.

Our global expansion may expose us to risks and uncertainties, including: (i) unfamiliarity with laws, regulations and policies, which may differ materially from those in jurisdictions we currently operate, including tax, employment, immigration and labor laws, rules and regulations promulgated by the Office of Foreign Assets Control and the U.S. Bureau of Industry and Security, as well as requirements to obtain overseas permits, licenses and approvals to manufacture, import, market and sell products in or to overseas jurisdictions; (ii) changes in a specific country’s or region’s political, cultural or economic environment, such as political instability, inflation, currency fluctuations, unexpected changes in tariffs, trade barriers, and regulatory requirements; (iii) our limited experience in and resource for commercializing our products in new markets; (iv) higher costs for new product development and reliance on potential overseas partners and/or their distribution network for the development, commercialization, marketing and distribution of our products; (v) potentially reduced protection for intellectual property rights and exposure to third-party patent rights in foreign jurisdictions; and (vi) business interruptions resulting from geopolitical actions or natural disasters. These and other risks may materially and adversely affect our ability to attain or sustain revenue from international markets.

Changes in the economic, political and other policies of the jurisdictions where we operate could have a material adverse effect on our business, financial condition and results of operations.

Our business, financial condition, results of operations and prospects are substantially affected by political, economic and legal developments both in the PRC and overseas markets where we operate. Economic growth in these markets has been uneven, varying both geographically and across different sectors within the economies. Government authorities in the PRC and other jurisdictions implement various measures to encourage economic growth. These measures may include differential policies towards specific groups of pharmaceutical companies, which may have an adverse effect on us. In addition, the overall economic growth in jurisdictions where we operate is influenced by government regulations and policies related to capital investments, monetary policies, regulation of financial services and institutions, and preferential treatment to particular industries or companies. Any changes in these regulations and policies could affect the business environment in the jurisdictions where we operate changes, thus impacting our business and growth prospects.

Furthermore, any economic downturn could create an uncertain economic outlook in markets where we currently operate or may operate in the future, which may adversely affect our business, financial condition and results of operations. Changes in the political environment could also increase our costs, heighten our exposure to legal and business risks, disrupt our operations and affect our results of operations.

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The current global geopolitical tension, particularly with regard to Sino-U.S. political and economic relations, may adversely impact our business, financial condition, and results of operations.

Recently, there have been heightened tensions in international political, trade and economic relations, as countries could enact sanctions, export controls, tariffs, investment controls or other measures, in particular, between the United States and China. For example, since early 2025, the U.S. government has through several rounds of increases, imposed higher tariffs on a wide range of goods imported from multiple countries. For details on additional U.S. tariffs on Chinese imports, see “Regulatory Overview—United States Laws and Regulations—U.S. Trade Related Regulations—U.S. Tariffs and Other Trade Restrictions.” During the Track Record Period and up to the Latest Practicable Date, we did not have any exports to, or generated any revenue from, the United States, and therefore were not subject to these additional U.S. tariffs on Chinese imports. Changing policies have created considerable uncertainty regarding future tariff rates and the trajectory of U.S.-China trade relations. It is unclear whether these challenges and uncertainties will be contained or resolved, and what effects they may have on the global political and economic conditions in the long term. Any continued tensions and the prospect of escalating tariffs could potentially impact the Chinese economy.

Separately, we may also be subject to review and enforcement under laws that screen foreign investment and acquisitions. For example, on January 2, 2025, a U.S. outbound investment security program, implemented by the U.S. Department of the Treasury under a newly adopted rule (the “Outbound Investment Rule”) on outbound investment, became effective. This rule imposes restrictions on U.S. outbound investment involving entities classified as “Covered Foreign Persons” under the Outbound Investment Rule. We do not believe our Company is a “Covered Foreign Person” as defined under the Outbound Investment Rule and therefore it will not be relevant to investments in our securities. For details, see “Regulatory Overview—United States Laws and Regulations—U.S. Trade Related Regulations—Regulations on Outbound Investment.” Subsequently, the U.S. government issued a broadly worded “America First Trade Policy” and an “America First Investment Policy” that seek to further restrict U.S. investments involving China (including possibly expanding technologies subject to investment restrictions, such as biotechnology, and narrowing related exceptions (including those related to publicly traded securities)). In addition, on December 18, 2025 the Comprehensive Outbound Investment National Security Act of 2025 (the “**COINS Act**”), became law. The COINS Act will supersede the Outbound Investment Rule following the adoption of implementing regulations, the content of which is uncertain. If our ability to raise capital from U.S. [REDACTED] is significantly and negatively affected by the Outbound Investment Rule (as it may be amended), the COINS Act or similar laws and regulations, it could be harmful to our business, financial condition and prospects.

When it comes to our industry in particular, certain Chinese biotechnology companies may become subject to legislation, trade restrictions, sanctions, and other regulatory requirements by the U.S. government, which could restrict or even prohibit our ability to collaborate with such entities. For example, the BIOSECURE Act was signed into law on December 18, 2025, which targets U.S. government contracts, grants, and loans for entities that use equipment and services from “biotechnology companies of concern.” If we, our suppliers, or our customers were to be designated as a “biotechnology company of concern,” this could potentially cause harm to our business and financial condition. For details of the BIOSECURE Act, see “Regulatory Overview—United States Laws and Regulations—U.S. Trade Related Regulations—U.S. Tariffs and Other Trade Restrictions.” In addition, the political landscape in the United States has affected U.S. government’s attitude towards China and may increase the likelihood of the imposition of further restrictions on biopharmaceutical companies that have substantial operations in China, particularly under the current U.S. administration. Our business is particularly susceptible to these controls and restrictions, and our financial condition and results of operations could be materially and adversely affected as a result.

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Laws and regulations on economic sanctions, export controls, anti-corruption, anti-bribery, anti-money laundering may expose us to potential compliance risks.

We are subject to laws and regulations on economic sanctions, export controls, anti-corruption, anti-bribery, anti-money laundering in China and other countries and regions where we operate. Any violation of these laws or regulations could result in governmental or regulatory investigations, civil or criminal fines or other sanctions, whistleblower complaints and adverse publicity, which could have an adverse effect on our reputation, business, operating results and prospects. Allegations of sanctions violations, even if untrue, could complicate our ability to work with international financial institutions, which could adversely affect our business operations, especially for our sales outside China. In addition, responding to any regulatory inquiry or enforcement action, regardless of the outcome, may result in a significant diversion of management's attention and resources, as well as significant defense costs and professional fees.

The United States, the United Kingdom and other jurisdictions or organizations, including the European Union and the United Nations, have, through executive orders, the passage of legislation or other governmental actions, implemented measures that impose economic sanctions or export control restrictions on certain countries or jurisdictions, persons or organizations within these countries or jurisdictions, or targeted industry sectors, groups of companies, or persons. Many of these measures are complex, and factors including limited available information regarding counterparties can make compliance with them difficult. There can be no assurance that we will be able to prevent or detect all inadvertent business dealings with sanctioned parties or the dispatch of products to high-risk counterparties or prohibited end-uses. We cannot predict the interpretation or implementation of government policies in the United States, the United Kingdom, the European Union and its member states, the United Nations, and other applicable jurisdictions with respect to any our current or future activities by us or our business partners, including sales or distribution of pharmaceutical products, in countries or regions now or in the future subject to international sanctions, or our business activities subject to export control restrictions. As a result, we cannot assure you that our future business will be free from risk under sanctions or export control restrictions implemented in these jurisdictions or that we will be able to conform our business to the evolving expectations and requirements of the authorities of the United States or any other government or organization that, with or without jurisdiction over our business, asserts the right to impose sanctions or export control restrictions on an extraterritorial basis. Our business and reputation could be adversely affected if the authorities of the United States, the United Kingdom, the European Union, the United Nations or any other government or organization were to determine that any of our activities constitute a violation of the sanctions or export control restrictions they impose or provide a basis for a sanctions designation or other restrictions on us. In addition, as sanctions programs are constantly evolving, new requirements or restrictions could come into effect that might increase regulatory scrutiny of our business or result in additional compliance risks.

We are subject to laws and regulations in the jurisdictions where we operate, and any failure to respond to future changes in the regulatory environment in these jurisdictions could have an adverse effect on our business, financial condition and results of operations.

We are subject to evolving laws and regulations governing the industry where we operate. Recently enacted laws and regulations may not comprehensively address all aspects of economic activities within our industry, and the interpretation and enforcement of such laws and regulations may be subject to uncertainties. We cannot predict the effect of future legislative developments in our industry, including the enactment of new laws, amendments to existing laws, or changes in the interpretation or enforcement, and the preemption of local regulations by national laws. Changes to laws and regulations applicable to our industry could result in new compliance requirements and unexpected challenges. The historical enforcement practices, or the lack thereof, may not be indicative of future regulatory actions. Any determination that we have failed to comply with applicable laws or regulations or any enforcement actions against us may result in interruption to our operations, substantial costs, or reputational harm.

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We are required to comply with other statutory requirements generally applicable to doing business in the PRC. For example, an employer is required under relevant PRC laws and regulations to pay the social insurance and housing provident fund contributions for its employees. During the Track Record Period, our Company and certain of our PRC subsidiaries did not make full social insurance and housing provident fund contributions for certain employees based on their actual wages. Consequently, we may be required to pay the outstanding amount and could be subject to overdue charges or fines. As of the Latest Practicable Date, we had not received any notice from the relevant authority in the PRC requiring us to pay shortfalls or imposing penalties related to social insurance and housing provident fund contributions. On the premise that there are no material changes to the prevailing laws, regulations and the implementation or supervisory requirements of the competent authorities, and that there are no material employee complaints, litigation or arbitration proceedings, our PRC Legal Advisor is of the view that the risk of us being subject to any material administrative penalty or centralized collection in respect of the above mentioned failure to make full contributions to social insurance and housing provident fund is remote. For details, see “Business—People and Culture—Social Insurance and Housing Provident Fund.” However, there can be no assurance that the competent authorities will not in the future require us to make additional contributions or impose penalties.

We are subject to privacy laws, information security policies and contractual obligations related to data privacy and security, and we may be exposed to risks related to our management of the medical data of subjects enrolled in our clinical trials and other personal or sensitive information.

We have access to and handle certain personal data in our business operations, and we need to comply with relevant data privacy and protection laws and regulations that apply to our data activities in the jurisdictions where we operate and conduct our clinical trials. For details, see “Business—Data Privacy and Protection.” In recent years, privacy and data protection has become an increasing regulatory focus of government authorities across the world. Particularly in China, where we operate substantially all our businesses, the PRC government has enacted a series of laws and regulations in respect of information security, data collection, privacy and protection. For detailed discussion on these applicable laws and regulations, see “Regulatory Overview—PRC Laws and Regulations—Regulations on Information Security and Data Privacy.” Non-compliance with laws or contractual obligation relating to data privacy, security and transfer could subject us to complaints, audits, investigations, sanctions, and proceedings by relevant government authorities or others, including class actions, which may subject us to significant fines, penalties and negative publicity and have material adverse impact on our competitive position, reputation, results of operations and prospects.

In addition, numerous U.S. federal and state laws and regulations relate to the privacy and security of personal information. In particular, regulations promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996 (the “HIPAA”) establish privacy and security standards that limit the use and disclosure of individually identifiable health information, known as “protected health information,” and require the implementation of administrative, physical and technological safeguards to protect the privacy of protected health information and ensure the confidentiality, integrity and availability of electronic protected health information. We may fail to handle protected health information in compliance with applicable privacy standards and our contractual obligations. For example, our information technology and infrastructure may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance or other malicious or inadvertent disruptions. Any such breach or interruption could compromise our networks and the information stored there could be accessed by unauthorized parties, manipulated, publicly disclosed, lost or stolen. Any such access, breach or other loss of information could result in legal claims or proceedings, and liability under federal or state laws that protect the privacy of personal information, such as the HIPAA, the Health Information Technology for Economic and

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Clinical Health Act, and regulatory penalties. Notice of breaches must be made to affected individuals, the Secretary of the Department of Health and Human Services, and for extensive breaches, notice may need to be made to the media or State Attorneys General. Such a notice could harm our reputation and our ability to compete.

We are also subject to restrictions on using human genetic resources collected in China. Under applicable laws and regulations, approval from the relevant human genetic resources authorities is required in international collaboration projects using China’s human genetic resources, except for in certain circumstances as otherwise provided. For detailed discussion on such laws and regulations, see “Regulatory Overview—PRC Laws and Regulations—Regulations on Human Genetic Resources.” We cannot assure you that we will be deemed at all times in full compliance with the applicable laws and regulations in our utilizing of and dealing with China’s human genetic resources. As a result, we may be exposed to compliance risks under these laws or regulations.

Additionally, cross-border transfer of personal data by its nature is subject to general data privacy regulations in various jurisdictions. Cross-border data transfer across different jurisdictions may be limited if we fail to comply with relevant requirements, such as obtaining authorization from subjects regarding the use, transfer and retrieval of their personal information or data and adopting measures to ensure the safety of personal information or data in the transfer. If we are unable to obtain necessary approvals or comply with the regulatory requirements in a timely manner, or at all, our R&D of drug candidates may be hindered. If the relevant government authorities consider the transmission of our scientific data or collection and usage of human genetic resources to be in violation of the requirements under applicable laws and regulations, we may be subject to fines and other administrative penalties imposed by those government authorities.

Laws and regulations on foreign currency conversion and the remittance of funds into and out of the PRC may affect our utilization of our revenue and our ability to remit dividends.

The PRC government imposes laws and regulations on the convertibility of the Renminbi into foreign currencies and, in certain cases, the remittance of funds into and out of the PRC, which may affect our utilization of our revenue and our ability to remit dividends. Under the existing PRC foreign exchange regulations, foreign exchange transactions under the current account conducted by us, including the payment of dividends, can be made in foreign currencies without prior approval of the State Administration of Foreign Exchange of the PRC (“SAFE”) by complying with certain procedural requirements and conduct such transactions at designated foreign exchange banks within the PRC that have the licenses to carry out foreign exchange business. Foreign exchange transactions under the capital account, however, normally need to be approved by or registered with the SAFE or its local branch unless otherwise permitted by law. Any insufficiency of foreign exchange may restrict our ability to satisfy our foreign currency demands, and we may not be able to pay dividends in foreign currencies to the [REDACTED] of our H Shares.

Fluctuations in exchange rates could result in foreign currency exchange losses and could materially and adversely affect our financial performance.

We generate part of our revenue from foreign jurisdictions and, consequently, are exposed to risks associated with foreign currency exchange fluctuations. Changes in the value of foreign currencies could increase our RMB costs for, or reduce our RMB revenues from, our foreign operations. Therefore, any fluctuations in the value of foreign currencies against RMB could materially and adversely affect our results of operations. In addition, the fluctuation of foreign exchange rates affects the value of our monetary and other assets and liabilities denominated in foreign currencies. We cannot guarantee that future foreign exchange rate fluctuations will be favorable, and any adverse change would not have a material adverse impact on our financial condition and results of operations.

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Dividends received by foreign holders of our H Shares and gains derived from the disposition of our H Shares by such holders may be subject to PRC taxation.

Under applicable PRC tax laws, regulations and statutory documents, non-PRC resident individuals and enterprises are subject to taxes with respect to dividends received from us or gains realized upon the sale or other disposition of our H Shares.

Under the PRC Individual Income Tax Law (《中華人民共和國個人所得稅法》) and its implementation rules, non-PRC resident individuals are generally subject to PRC individual income tax with respect to PRC-sourced income or gains at a rate of 20% unless specifically exempted by the tax authority of the State Council or reduced or eliminated by an applicable tax treaty. We are required to withhold related tax from dividend payments. In addition, non-PRC resident enterprises that do not have establishments or premises in the PRC, or that have establishments or premises in the PRC but their income is not effectively connected to such establishments or premises, are subject to the enterprise income tax of the PRC at the rate of 10% on dividends received from PRC companies and gains realized upon disposition of equity interests in the PRC companies pursuant to the EIT Law and other applicable PRC tax regulations and statutory documents, unless a treaty or similar arrangement provides otherwise. Taxes may be reduced or eliminated under special arrangements or applicable treaties between the PRC and the jurisdiction where the non-resident enterprise resides. For details, see “Appendix III Taxation and Foreign Exchange—1. Taxation of Security Holders—A. The PRC Taxation.” If PRC income tax is imposed on gains realized from the transfer of our H Shares or on dividends paid to our non-PRC resident individuals, the value of your [REDACTED] in our H Shares may be affected. Furthermore, our Shareholders whose jurisdictions of residence have tax treaties or arrangements with PRC may not qualify for benefits under such tax treaties or arrangements.

You may experience difficulty in effecting service of legal process or enforcing foreign judgments in the PRC against us or our Directors or senior management members named in this document.

Substantially all of our business operations are conducted in the PRC, and a substantial majority of our Directors and senior management members reside in the PRC. Therefore, it may be difficult for [REDACTED] to effect service of legal process within the PRC upon those persons or to enforce against us or them any judgments obtained from non-PRC courts. The PRC does not have treaties providing for the reciprocal recognition and enforcement of judgments of courts of most foreign jurisdictions. As a result, the recognition and enforcement in the PRC of judgments of a court in a jurisdiction outside the PRC may be difficult or impossible.

On July 14, 2006, the Supreme People’s Court of the PRC and the Government of the Hong Kong Special Administrative Region (the “**Hong Kong SAR Government**”) signed the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters (the “**Choice of Court Arrangement**”). Under the Choice of Court Arrangement, a party with an enforceable final court judgment rendered by any designated people’s court in the PRC or any designated Hong Kong court requiring payment of money in a civil and commercial case according to a written choice of court agreement, may apply for recognition and enforcement of the judgment in the relevant PRC or Hong Kong court. A written choice of court agreement is defined as any agreement in writing entered into between the parties concerned in which a Hong Kong court or a PRC court is expressly designated as the court having sole jurisdiction over the dispute.

On January 18, 2019, the Supreme People’s Court of the PRC and the Hong Kong SAR Government signed the Arrangement on Reciprocal Recognition and Enforcement of Judgments in Civil and Commercial Matters by the Courts of the Mainland and of the Hong Kong Special Administrative Region (the “**REJ Arrangement**”), which became effective on January 29, 2024. The REJ Arrangement supersedes the Choice of Court Arrangement and establishes a more

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comprehensive mechanism for reciprocal recognition and enforcement of judgments in a wider range of civil and commercial matters between Chinese Mainland and Hong Kong. Unlike the Choice of Court Arrangement, which requires a written choice of court agreement expressly designating a Hong Kong or PRC court as having sole jurisdiction, the REJ Arrangements allows for recognition and enforcement without such agreement. However, the Choice of Court Arrangement continues to apply to a written choice of court agreement made between the parties concerned before the effective date of the REJ Arrangement. Although the REJ Arrangement has become effective, the outcome of any action brought under the REJ Arrangement may be uncertain, and we cannot assure you that an effective judgment that complies with the REJ Arrangement will be recognized and enforced in a PRC court. Accordingly, it may remain difficult or impossible for [REDACTED] to effect process against our assets or management in the PRC or to seek recognition and enforcement of foreign judgments in the PRC.

RISKS RELATED TO THE [REDACTED]

We will be concurrently subject to [REDACTED] and regulatory requirements of the PRC and Hong Kong.

As we are listed on the Shenzhen Stock Exchange and will be [REDACTED] on the [REDACTED], we will be required to comply with the listing rules (where applicable) and other regulatory regimes of [REDACTED], unless an exemption is available. Accordingly, we may incur additional costs and resources in continuously complying with all applicable listing rules and other regulatory regimes in the [REDACTED].

Our A Shares are listed on the Shenzhen Stock Exchange. The characteristics of the A Share and H Share markets may differ.

Our A Shares are listed and traded on the Shenzhen Stock Exchange. Following the [REDACTED], our A Shares will continue to be traded on the Shenzhen Stock Exchange and our H Shares will be [REDACTED] on the [REDACTED]. Under the current PRC laws and regulations, our H Shares and A Shares are neither interchangeable nor fungible, and there is no trading or settlement between the H Share and A Share markets. The H Share and A Share markets have different trading characteristics, each having different [REDACTED], as well as different levels of retail and institutional [REDACTED] participation. As a result, the [REDACTED] of our H Shares and A Shares may not be comparable, and the historical prices of our A Shares may not be indicative of the [REDACTED] of our H Shares. Nonetheless, fluctuations in the price of our A Shares may adversely affect the [REDACTED] of our H Shares, vice versa. Therefore, you should not place undue reliance on the trading history of our A Shares when evaluating the [REDACTED] decision in our H Shares.

There has been no prior [REDACTED] for our H Shares, and their [REDACTED] and [REDACTED] may be volatile, which could lead to substantial losses to [REDACTED].

Prior to the completion of the [REDACTED], there has been no [REDACTED] for our H Shares. We cannot assure you that a [REDACTED] for our H Shares with adequate [REDACTED] and [REDACTED] will develop and be sustained following the completion of the [REDACTED]. The [REDACTED] for our H Shares to the [REDACTED] will be the result of negotiations between us and the [REDACTED] (for themselves and on behalf of the [REDACTED]), and the [REDACTED] may differ significantly from the [REDACTED] of our H Shares following the completion of the [REDACTED]. We have applied to the [REDACTED] for the [REDACTED] of, and permission to [REDACTED] in, the H Shares. A [REDACTED] on the [REDACTED], however, does not guarantee that an active and liquid [REDACTED] for our H Shares will develop, or if it does develop, that it will be sustained following the [REDACTED], or that the [REDACTED] of our H Shares will not decline following the [REDACTED].

RISK FACTORS

Furthermore, the [REDACTED] and [REDACTED] of our H Shares may be volatile. Various factors may affect the [REDACTED] and [REDACTED] at which our H Shares will [REDACTED], including: variations in our revenue, earnings and cash flow; announcement of new investments, business collaborations, strategic alliances or acquisitions; any unexpected business interruptions resulting from epidemics, natural disasters or power shortages; any major changes in our Directors, senior management or other key personnel; our inability to obtain or maintain regulatory approval for our operations; our inability to compete with our competitors effectively; political, economic, financial and social developments; or fluctuations in market prices for our products or raw materials. Moreover, shares of other companies listed on the Stock Exchange with operations and assets in China have experienced significant price volatility in the past. It is possible that our H Shares may be subject to changes in [REDACTED] not directly related to our performance and as a result, [REDACTED] in our H Shares may suffer substantial losses.

Future sales or perceived sales of substantial amounts of our Shares in the [REDACTED] could negatively affect the [REDACTED] of our Shares and our ability to raise additional capital in the future.

The [REDACTED] of our H Shares could decline as a result of future sales of a substantial number of our Shares or other securities relating to our H Shares in the [REDACTED], the issuance of new shares or other securities, or the perception that such sales or issuances may occur. Future sales, or perceived sales, of substantial amounts of our securities, including any future offerings, could also materially and adversely affect our ability to raise capital at a specific time and on terms favorable to us. Equity-linked securities issued by us may also confer rights and privileges that take priority over those conferred by the Shares.

[As the [REDACTED] of our H Shares is higher than our consolidated net tangible asset per Share, [REDACTED] of our H Shares in the [REDACTED] may experience immediate dilution upon such purchases.

As the [REDACTED] of our H Shares is higher than the consolidated net tangible assets per Share immediately prior to the [REDACTED], [REDACTED] of our H Shares in the [REDACTED] may experience an immediate dilution. Our existing Shareholders will receive an increase in the [REDACTED] per Share of their Shares. In addition, holders of our H Shares may experience further dilution of their interest if we [REDACTED] additional H Shares in the future to raise additional capital.]

Our Controlling Shareholders may have substantial influence over our Company and their interests may not be aligned with the interests of other Shareholders.

Our Controlling Shareholders may have substantial influence over our business, including matters relating to our management, policies and decisions regarding mergers, expansion plans, consolidations and sales of all or substantially all of our assets, election of Directors and other significant corporate actions. Immediately following the completion of the [REDACTED], our Controlling Shareholders will be entitled to exercise approximately [REDACTED]% of the issued share capital of our Company. This concentration of ownership may discourage, delay or prevent a change in control of our Company, which could deprive other Shareholders of an opportunity to receive a premium for their H Shares as part of a sale of our Company and might reduce the [REDACTED] of our H Shares. These events may occur even if they are opposed by our other Shareholders. In addition, the interests of our Controlling Shareholders may differ from the interests of our other Shareholders. It is possible that our Controlling Shareholders may exercise their influence over us and cause us to enter into transactions or take, or fail to take, actions or make decisions that conflict with the best interests of our other Shareholders.

RISK FACTORS

You should not place any reliance on any information released by us in connection with the listing of our A Shares on the Shenzhen Stock Exchange.

As our A Shares are listed on the Shenzhen Stock Exchange, we have been subject to periodic reporting and other information disclosure requirements in the PRC. As a result, from time to time, we publicly release information relating to us on the Shenzhen Stock Exchange or other media outlets designated by the CSRC. However, the information announced by us in connection with our A Shares listing is based on regulatory requirements of the securities authorities, industry standards and market practices in the PRC, which are different from those applicable to the [REDACTED]. The presentation of financial and operational information for the Track Record Period disclosed on the Shenzhen Stock Exchange or other media outlets may not be directly comparable to the financial and operational information contained in this document. Therefore, prospective [REDACTED] in our H Shares should be reminded that, in making their [REDACTED] decisions as to whether to [REDACTED] in our H Shares, should rely only on the financial, operating and other information included in this document. By applying to [REDACTED] our H Shares in the [REDACTED], you will be deemed to have agreed that you will not rely on any information other than that contained in this document and any formal announcements made by us in Hong Kong with respect to the [REDACTED].

[REDACTED]

Certain facts, forecasts and other statistics in this document are derived from various official government sources, which have not been independently verified and may not be reliable.

Certain facts, forecasts and other statistics in this document are derived from various official government sources. However, our Directors cannot guarantee the quality or reliability of such source materials. We believe that the sources of the said information are appropriate sources for such information and have taken reasonable care in extracting and reproducing such information. We have no reason to believe that such information is false or misleading or that any fact has been omitted that would render such information false or misleading. Nevertheless, information from official government sources has not been independently verified by us, the Joint Sponsors, [REDACTED] or any of their respective affiliates or advisors and, therefore, we make no representation as to the accuracy of such facts and statistics. Furthermore, we cannot assure our [REDACTED] that they are stated or compiled on the same basis or with the same degree of accuracy as similar statistics presented elsewhere. In all cases, our [REDACTED] should consider carefully how much weight or importance should be attached to or placed on such facts or statistics.

RISK FACTORS

You should read the entire document carefully and only rely on the information included therein, and we strongly caution you not to place any reliance on any information contained in press articles or other media regarding ourselves and the [REDACTED].

We may be subject to press and media coverage prior to the publication of this document, and subsequent to the date of this document but prior to the completion of the [REDACTED]. The press and media may include certain financial information, industry comparisons, profit forecasts and other information about us that does not appear in this document.

You should rely solely upon the information contained in this document, the [REDACTED] and any formal announcements made by us in Hong Kong in making your [REDACTED] decision regarding the H Shares. We do not accept any responsibility for the accuracy or completeness of any information reported by the press or other media, nor the fairness or appropriateness of any forecasts, views or opinions expressed by the press or other media regarding ourselves or the [REDACTED].

We make no representation as to the appropriateness, accuracy, completeness or reliability of any such information, reports or publications. Accordingly, prospective [REDACTED] should not rely on any such information, reports or publications in making their [REDACTED] decisions regarding the [REDACTED]. By [REDACTED] our H Shares in the [REDACTED], you will be deemed to have agreed that you will not rely on any information other than that contained in this document, the [REDACTED] and any formal announcements made by us in Hong Kong.